

REMARKS

Claims 1-10 and 27-54 are pending in the application with entry of this amendment. Claims 1, 27, 30 and 47 are currently amended. The amendments do not present new matter since coagulation and stimulation elements for respectively forming and evaluating tissue lesions are described throughout the specification. *See, e.g.*, p. 25, lines 7-20 (after the lesion is formed, a physician may use the same surgical device that was used to form the lesion to perform lesion evaluation utilizing stimulation electrodes); p. 26, lines 11-314 (coagulation electrodes may be used to form continuous lesions; stimulation electrodes may then be used to provide stimulation energy to the area within the lesion, and the tissue on the other side of the lesion may be monitored to determine whether the excitation block formed by the lesion is complete); p. 26, line 32 – p. 27, line 11 (stimulation electrodes may be used to test the quality and depth of lesions). Applicant notes that there is no requirement that a claim amendment must include exactly the same nomenclature as provided in the specification and support for claim amendments can be supported by express, inherent or implicit disclosure. MPEP §608.01(o); MPEP §2163 (While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure). Claims 11-26 were previously canceled. Claims 7, 37 and 38 are withdrawn from consideration. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicant acknowledges that all of the prior rejections based on U.S. Patent No. 6,010,500 to Sherman *et al.* and U.S. Patent No. 6,889,694 to Hoooven have been withdrawn. The pending claims stand rejected based on new grounds of rejection and new cited references.

II. Claims 1-7, 9-10, 27-34, 36, 39-47 and 49-54 Are Novel Over Maguire

Independent claims 1, 27, 30 and 47 and respective dependent claims 2-7, 9, 10, 28-29, 31-34, 36, 39-46 and 49-54 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,755,760 to Maguire *et al.* (hereafter “Maguire”) A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Applicant respectfully traverses the rejection.

Maguire fails to disclose, teach or suggest the combination of “a coagulation element configured to emit energy for coagulating tissue and forming a lesion within tissue, the coagulation element defining a coagulation element configuration on the distal region of the

relatively short tubular shaft” and “a stimulation element configured to emit energy for stimulating tissue and evaluating formation of the lesion, the stimulation element defining a stimulation element configuration on the distal region of the same relatively short tubular shaft, the stimulation element configuration being different than the coagulation element configuration” as recited in claims 1, 27 and 30 and the combination of “means for coagulating tissue on the distal region of the relatively short tubular shaft and forming a lesion within tissue” and “means, having a different configuration than the means for coagulating tissue, for stimulating tissue on the distal region of the same relatively short tubular shaft and evaluating formation of the lesion” as recited in claim 47.

It is alleged in the Office Action that the coil electrodes 12 and/or 16 define “a coagulation element configuration,” and that the electrode 20 and alternate components define “a stimulation configuration.” Office Action (p. 2). However, this is not what is actually described by Maguire. Instead, Maguire actually explains that the electrode 20 is a cardiac mapping electrode. Maguire (col. 3, lines 51-52; col. 4, lines 47-48). As is well understood, a cardiac mapping electrode serves as a sensor or antenna for detecting electrical activity of the heart. *See, e.g.,* U.S. Patent No. 6,063,080 (col. 1, lines 38-50) (cited by Office Action), which explains that cardiac mapping is used to identify a potential ablation site. This procedure involves inserting a catheter having multiple electrodes into the heart and monitoring the electrical signals of the heart in order to identify tissue causing an arrhythmia. In this manner, cardiac mapping electrodes “serve as individual antennas for detecting the electrical activity of the heart in the area corresponding to that electrode. The description of a cardiac mapping electrode and the understanding of persons of ordinary skill in the art have not been addressed or reconciled by the Office Action. *See also*, U.S. Patent Nos. 5,964,753 and 6,360,128 (providing other similar descriptions of cardiac mapping procedures and electrodes) (“Cardiac mapping can be used before ablation to locate aberrant conductive pathways within the heart. The aberrant conductive pathways constitute peculiar and life threatening patterns, called dysrhythmias. Mapping identifies regions along these pathways, called foci, which are then ablated to treat the dysrhythmia.”).

Therefore, a cardiac mapping electrode 20 described by Maguire is not “a stimulation element configured to emit energy for stimulating tissue and evaluating formation of the lesion” as recited in claims 1, 27 and 30 since, as described above, the cardiac mapping electrode 20 does not emit energy and does not emit energy for stimulating tissue. Further, a cardiac mapping

electrode 20 as described by Maguire is not “means, ... for stimulating tissue on the distal region of the same relatively short tubular shaft and evaluating formation of the lesion” as recited in claim 47. In this regard, a cardiac mapping electrode operates in a manner that is the opposite of a stimulation element that emits energy. In fact, Maguire does not even refer to evaluating a tissue lesion and the Office Action understandably has not cited any section of Maguire related to these types of devices. Thus, it is well understood that a stimulation element as recited in claims 1, 27 and 30 and a means for stimulating tissue as recited in claim 47 are fundamentally different than a cardiac mapping electrode. Accordingly, Maguire does not support, and contradicts, the Office Action allegations. If the rejection stands following this Amendment, Applicant respectfully requests the Examiner to specify, by paragraph and line number (and words and specific components thereof), where Maguire actually describes what is alleged since Applicant is not able to identify such a description in the cited paragraphs, particularly in view of the known manner in which cardiac mapping electrodes 20 operate.

Given the clear deficiencies of Maguire, it must be alleged that Maguire inherently discloses a “stimulation element” as recited in claims 1, 27 and 30 and “means ... for stimulating tissue” as recite in claim 47. However, the rejection cannot stand since the Office Action has provided no explanation and has presented no extrinsic evidence to establish that a known cardiac mapping electrode 20 as described by Maguire operates in a manner that is essentially the opposite of its known manner of operation and instead is “a stimulation element configured to emit energy for stimulating tissue and evaluating formation of the lesion, the stimulation element defining a stimulation element configuration on the distal region of the same relatively short tubular shaft, the stimulation element configuration being different than the coagulation element configuration” as recited in claims 1, 27 and 30 and “means, having a different configuration than the means for coagulating tissue, for stimulating tissue on the distal region of the same relatively short tubular shaft and evaluating formation of the lesion” as recited in claim 47.

Accordingly, the Office Action has not satisfied the inherency requirements and cannot support the rejection since the Office Action relies on allegations that are not supported by, and are inconsistent with, what is actually described by Maguire and the known manner in which a cardiac mapping electrode 20 operates. MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain

thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art; a claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present) (emphasis added).

In view of these substantial differences and deficiencies, Applicant respectfully submits that Maguire does not anticipate independent claims 1, 27, 30 and 47 under §102(b). Dependent claims 2-7, 9, 10, 28-29, 31-34, 36, 39-46 and 49-54 incorporate the elements and limitations of respective independent claims 1, 27, 30 and 47 and, therefore, are also novel over Maguire for at least the same reasons.

Additionally, Maguire fails to disclose, teach or suggest other “stimulation element” and “stimulation electrode” and related elements of various dependent claims including claims 2, 4, 5, 10, 28, 29, 30, 31, 33, 36, 39, 40, 42, 43, 44, 46 and 50 since, as discussed in detail above, it is well known that a cardiac mapping electrode is not a stimulation element or electrode, does not utilize stimulation energy, does not utilize a stimulation energy source, and the Office Action has not established that the cardiac mapping electrode 20 described by Maguire inherently or necessarily operates in a manner that is the opposite of which the cardiac mapping electrode operates.

Maguire is also deficient relative to claim 28, which recites *inter alia* “a stimulation energy line connected to the stimulation element and to a stimulation energy connector configured to be connected to the source of stimulation energy.” As discussed above, it is well known that a cardiac mapping electrode does not utilize stimulation energy and, therefore, does not have, utilize, or require, a stimulation energy line, a stimulation energy connector, or a source of stimulation energy. Similar remarks apply to claim 36 since Maguire does not disclose, teach or suggest a source of stimulation energy as recited in claim 36. Again, general allegations that contradict what is actually described by Maguire cannot support the rejection.

In view of the above remarks and deficiencies of Maguire, Applicant respectfully requests that the rejection of claims 1-7, 9-10, 27-34, 36, 39-47 and 49-54 under 35 U.S.C. §102(b) be withdrawn.

III. Claims 8, 35 and 48 Are Patentable Over Maguire and Nelson

Dependent claims 8, 35 and 48 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of U.S. Patent No. 6,063,080 to “Haissaguerre.” Office Action (p. 5). Applicant notes that the Office Action refers to Haissaguerre, but U.S. Patent No. 6,063,080 names Nelson as an inventor, and the Notice of References Cited also refers to Nelson. Thus, it is Applicant’s understanding that the Office Action intended to refer to U.S. Patent No. 6,063,080 to Nelson rather than to Haissaguerre. Clarification is respectfully requested if Applicant’s understanding is not correct.

It is conceded in the Office Action that Maguire fails to disclose at least a portion of a distal region of a relatively short tubular being malleable. Office Action (p. 5). Nelson is cited for the very limited purpose of allegedly disclosing this element with regard to only three dependent claims. Nelson, however, does not cure the substantial deficiencies of Maguire discussed above. Thus, the two cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each element of claims 1, 8, 27, 35, 47, 48.

Accordingly, Applicant respectfully requests that the rejection of claims 8, 35 and 48 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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